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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
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| 10/034,350      | 01/03/2002  | Maurice Zauderer     | 1821.0010002/EKS/HCC | 7983             |

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EXAMINER

VANDERVEGT, FRANCOIS P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

DATE MAILED: 07/17/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/034,350             | ZAUDERER, MAURICE   |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | F. Pierre VanderVegt   | 1644                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a divisional of U.S. Application Serial Number 08/935,377.

Claims 1-38 have been canceled previously.

Claims 39-88 are currently pending and are the subject of examination in the present Office Action.

#### *Election/Restrictions*

1. Applicant's election without traverse of the species (A) a viral source of heterologous nucleic acids, (B) host cells that express MHC Class I, (C) a vaccinia vector, (D) a transfer plasmid comprising p7.5/ATG1/tk, and (E) a fowlpox virus as a helper virus in Paper No. 8, filed April 25, 2003, is acknowledged.

Accordingly, claims 39-42 and 45-88 read upon elected species. However, upon further review, the species election requirement is hereby withdrawn and claims 39-88 are the subject of examination in the present Office Action.

#### *Specification*

2. The abstract of the disclosure is objected to because the page comprising the Abstract of the Disclosure also contains the original title of the application, which was replaced in Applicant's preliminary amendment filed January 3, 2002. It is suggested that Applicant submit a replacement page which does not recite any title.

Correction is required. See MPEP § 608.01(b).

#### *Drawings*

3. Drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

#### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

##### **A. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or

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docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. *The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.*

**B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

4. Applicant is reminded to amend the Brief Description of the Drawings to reflect the numbering used in the Figures. In addition, if any individual panel is described (e.g., Figure 1A), then all individual panels must be described. MPEP 608.01(f).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. Claims 39-84, 86 and 88 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "recovering those host cells" that have released from the monolayer, does not reasonably provide enablement for recovering the full scope of cells "which have undergone a lytic event" through the action of cytotoxic T cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Briefly, the claimed invention is drawn to a method of selecting nucleic acid molecules which encode a target epitope of T cells by engineering host cells to express the target epitope in context of MHC, incubating the host cells with a T cell specific for the epitope, and collecting those cells which were damaged by the T cells. The claim describes the damaged host cells as being those that "have undergone a lytic event" in step (b). However, the specification teaches only the recovery of whole cells from a surface-immobilized monolayer that have detached after incubation with cytotoxic T cells, not the collection of all products of cell lysis. Applicant is reminded that the phrase "recovering those host cells which have undergone a lytic event" recited in the base claim must be given it's broadest reasonable

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interpretation, which would include host cells at all stages of lysis, including host cells that have been completely lysed. Because completely lysed cells are no longer whole cells, it would require undue experimentation to recover said completely lysed host cells in accordance with the disclosed methods without further guidance and direction from the instant specification. In view of the breadth of the claims and the amount of guidance provided in the specification, it would require an undue amount of experimentation on the part of the artisan to practice the claimed invention.

6. Claims 39-44 and 46-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 is incomplete in that the claim is drawn to "selecting a nucleic acid molecule encoding a target epitope..." in the preamble of the claim without the presence of a resolution step in the claim meeting that limitation. In order to "select" the nucleic acid, it must be purified from the collected host cells. This rejection can be overcome by adding a nucleic acid purification step and a summary statement in the claim to the effect of "thereby selecting a nucleic acid molecule encoding a target epitope..." Dependent claims 40-42 and 46-88 are included in this ground of rejection.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 39-88 are provisionally rejected under the judicially created doctrine of double patenting over claims 68-70, 79-91, 98-100 and 104-120 of copending Application No. 08/935,377. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

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Claim 68 of the '377 application is identical to base claim 39 of the instant application, save for the absence of the instant limitation reading on the elected species that the target epitope is selected from an infected cell or an epitope specific to an autoimmune disease (including instant claims 40-44). However, since claim 68 of the '377 application is not so limited and the specification thereof discloses that the method can be applied to a target epitope selected from an infected cell or is specific for an autoimmune disease (page 16, lines 10-16 for example).

Claims 69 and 70 of the '377 application further recite the isolation of the vector from the recovered host cells (45) and claim 70 recites transferring same to a second population of host cells (46).

Claim 68 of the '377 application also recites that the vector is a vaccinia virus and claim 70 recites host cells which are mammalian – and therefore permissive for the production of infective particles by the vaccinia (47-54).

Claims 79-91 of the '377 application recite a transcriptional control signal which is a constitutive vaccinia p7.5 or early/late promoter and translational control, initiation and termination, in operable association with the heterologous nucleic acid (55-62).

Claims 98-100 and 104-111 of the '377 application recite the construction of the library, that the helper virus is the avipox virus fowlpox and the identity and location of the restriction sites (63-79).

Claims 112-116 of the '377 application recite the identity of the viral genome as v7.5/tk or vEL/tk and the transfer plasmid as including the elected p7.5/ATG1/tk species (80-84).

Claims 117 and 119 of the '377 application recite that the host cells are in a monolayer and a lytic event releases them from same (85 and 87).

Claims 118 and 120 of the '377 application recite that the host cells are MHC Class I (86 and 88).

### *Conclusion*

9. No claim is allowed.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette,

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1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
July 15, 2003

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600